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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,415	06/22/2006	Arjan van der Plaats	39612 3606	
86378 Pearne & Gordo	7590 04/28/200 on LLP	EXAMINER		
1801 East 9th S	treet	HENKEL, DANIELLE B		
Suite 1200 Cleveland, OH 44114-3108			ART UNIT	PAPER NUMBER
			1797	
			NOTIFICATION DATE	DELIVERY MODE
			04/28/2009	ELECTRONIC

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patdocket@peame.com dchervenak@peame.com

	Applica	tion No.	Applicant(s)				
Office Action Summary		415	PLAATS ET AL.				
		er	Art Unit				
		LE HENKEL	1797				
The MAILING DATE of this commun Period for Reply	ication appears on t	he cover sheet with the c	correspondence ad	idress			
A SHORTENED STATUTORY PERIOD F WHICHEVER IS LONGER, FROM THE M - Extensions of time may be available under the provisions after SIX (6) MONTHS from the mailing date of this comn - If NO period for reply is specified above, the maximum states - Failure to reply within the set or extended period for reply Any reply received by the Office later than three months a earned patent term adjustment. See 37 CFR 1.704(b).	AILING DATE OF 7 of 37 CFR 1.136(a). In no a nunication. atutory period will apply and will, by statute, cause the a	THIS COMMUNICATION event, however, may a reply be tin will expire SIX (6) MONTHS from oplication to become ABANDONE	N. nely filed the mailing date of this c D (35 U.S.C. § 133).				
Status							
1)⊠ Responsive to communication(s) file	d on 30 December	2008.					
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<i>'</i>	, <del></del>						
,	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4)⊠ Claim(s) <u>1-8</u> is/are pending in the ap	plication.						
4a) Of the above claim(s) is/a	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.	<u> </u>						
6)⊠ Claim(s) <u>1-8</u> is/are rejected.	·						
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restric	tion and/or election	requirement.					
Application Papers							
9)☐ The specification is objected to by the	e Examiner.						
10)⊠ The drawing(s) filed on <u>30 January 2006</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (F 3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date		4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal F 6) Other:	(PTO-413) ate				

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#### **DETAILED ACTION**

### Response to Amendment

- 1. The amendment filed December 30, 2008 has been entered and fully considered.
- 2. The objection to the drawings has been withdrawn in light of Applicant's amendment.
- 3. Claims 1-8 are pending.

## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

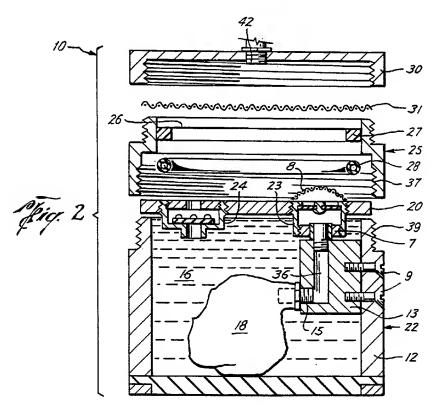
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 1-3, 5, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by O'DELL (US 5385821).
  - a. With respect to claim 1, ODELL teaches a portable preservation apparatus of the cold storage type for a donor organ (Figure 2) comprising: a cooling box (chamber, 10) (Column 3, lines 14-25 and Column 5, line 28), an organ chamber in the cooling box for receiving a donor organ in preservative fluid (perfusing compartment 25) (Column 5, line 29); a lid (30) for the cooling box having a side which operatively faces the organ chamber (Column 5, lines 43-44); at least one perfusion pump (32) mounted at least partly in the lid (Column 5, lines 44-46); a connector (22&25) detachably connected to the lid (threaded attachment)

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(Column 7, lines 7-18) on the side of the lid which operatively faces the organ chamber, which connector is provided with passages (valves 23, 24), one or more connecting pieces (36 &15) for connection with a donor organ in the organ chamber (Column 6, lines 65-67) and extending through one or more of the passages, and with one or more fluid pipes (25) connected with the at least one perfusion pump; at least one oxygenator (Column 3, lines 38-44); an oxygen container (Column 3, lines 20-21); one or more electronic modules and power supply module (Column 8, lines 7-16).



b. With respect to claim 2, ODELL teaches the connector has the form of a container open on one side (25), and is provided with fastening elements (threading, latches, etc) which can cooperate with fastening elements provided to

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the lid for fastening the connector to the lid in such a detachable manner that the open side of the container faces the lid, while the passages are located in an otherwise closed wall (20) facing the organ chamber (Figure 2, Column 7, lines 7-18).

- c. With respect to claim 3, ODELL teaches all part of the device coming into contact with preservative fluid are mounted in the connector, so that, together with the said at least one oxygenator, said at least part of the at least one perfusion pump coming into contact with the preservative fluid and said corresponding fluid pipes, all mounted in the connector, the connector forms a single-use replacement part (Figure 2).
- d. With respect to claim 5, ODELL teaches the lid for the cooling box is provided with at least one of the one or more electronic modules (Figure 2).
- e. With respect to claim 7, ODELL teaches the one or more electronic modules comprises a minicomputer (logic device) (Column 8, lines 7-16).
- f. With respect to claim 8, ODELL teaches the outside of the connector, near the wall facing the organ chamber, the connector is provided with a number of circumferential grooves and or ribs for fastening an organ chamber (Figure 2, Column 7, lines 24-33).

# Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'DELL (US 5385821).
  - a. With respect to claim 4, ODELL teaches the at least one perfusion pump is a pump with a detachable driving motor (32), which driving motor is, in mounted condition, located on the side of the lid for the cooling box facing away from the connector and is connected with the remaining part of the pump via an

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opening in the lid for the cooling box, which remaining part of the pump is mounted in the connector (Figure 2). ODELL does not explicitly disclose the driving motor is detachably connected with the rest of the pump, however it would have been obvious to one of ordinary skill in the art at the time of the invention to make the motor detachable, since it has been held that construction a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichtnan.* 168 USPQ 177, 179.

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- 10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'DELL (US 5385821) in view of OWEN (US 6673594).
  - a. With respect to claim 7, ODELL teaches a cover on the lid (114) (Figure 9), but does not explicitly disclose this cover at least partly forms a window for a display screen. However, OWEN teaches an organ perfusion apparatus in which an embodiment of the organ container has an inner and outer lid (cover) (Column 10, lines 41-42) that are construction of an optically clear material (window) (Column 10, lines 59-60). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of ODELL to include a window in the cover over the lid, as taught by OWEN because it allows for viewing the interior of the chamber to monitor the progress and status of the organ (Column 10, lines 60-63).

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### Response to Arguments

11. Applicant's arguments with respect to claims 1-6 and 8 have been considered but are most in view of the new ground(s) of rejection.

12. Applicant's arguments in response to claim 7, filed 12/30/2008 have been fully considered but they are not persuasive. In response to applicant's argument that the window for observing a display as claimed is not obvious over the window for observing the interior of the organ chamber of OWEN, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

### Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 11am-8pm, Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/ Primary Examiner, Art Unit 1797

/DANIELLE HENKEL/ Examiner, Art Unit 1797 Application/Control Number: 10/566,415

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